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Patent
147117-100002 TFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.: 10/014,977	)	**Confirmation No. 3321**
Applicant: Michael Webber	)	
Filed: December 10, 2001	)	
TC/AU: 3736	)	
Examiner: R. Nasser	)	
Docket No. 147117-100002	)	
Customer No. 34026	)	

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Applicants hereby enclose for filing an Appeal Brief (in triplicate) for the above referenced application.

The items checked below are appropriate:

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Fay Lum-Lee
Name of Person Mailing Paper

August 26, 2005
Date of Deposit

Fay Lum-Lee
Signature of Person Mailing Paper

☒ **"Small Entity Status"** of this application under 37 CFR 1.9 and 1.27 has been claimed.

FEE FOR FILING A BRIEF IN SUPPORT OF AN APPEAL

Pursuant to 37 CFR 1.17(c), the fee for filing the Appeal Brief is:

☐	other than a small entity	$500.00
☒	small entity	$250.00
	Appeal Brief Fee Due:	$250.00

☐ A check in the amount of is enclosed to cover the above fee(s).

☒ Charge Jones Day's Deposit Account No. **50-2468** in the amount of **$250.00**.

☒ The Commissioner is authorized to charge Jones Day's Deposit Account No. **50-2468** for any fees required under 37 CFR §§ 1.16 and 1.17 that are not covered, in whole or in part, by a check enclosed herewith and to credit any overpayments to said Deposit Account **50-2468**.

Respectfully submitted,

JONES DAY

Dated: August 26, 2005

By: _____
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APPEAL BRIEF

Real Party In Interest

The real party in interest is Pranalytica, Inc., located at 1101 Colorado Boulevard in Santa Monica, California. An assignment by Appellant Dr. Michael Webber to Pranalytica of this application was recorded on April 4, 2002 (Reel/Frame: 012771/0169).

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Related Appeals and Interferences

Neither Appellant nor Appellant's assignee or attorney are aware of another Appeal or Interference that will affect or have a bearing on the Board's decision of this Appeal.

Status of Claims

Claims 1, 4-6, 8-11, 13, 14, 17-22, 24-26, 29-34, 36, 37 and 39-42 are rejected. No claims are allowed.

Status of Amendments

No Amendment has been filed subsequent to the Final Rejection in this case.

Summary of Invention

The invention is a method of analyzing alveolar breath (page 5, paragraph 0012) by measuring the light energy absorbed by a first component of breath, followed by spectroscopic measurement of a second breath component based on the concentration of the first breath component in a previous expired breath (page 6, paragraph 0017).

Most humans have a lung capacity of about 5 to 6 liters. Of this volume, only about 0.3 liters is involved with the gas exchange between blood and breath in the lungs. This exchange takes place in a portion of the lung termed the alveoli. This 0.3 liters of breath is called alveolar breath. The concentration of gas components in alveolar breath closely reflect the concentration of these same gas components in blood (page 1, paragraph 0002).

Taking as an illustrative example a situation where the first breath component is CO_2 and the second is ammonia, ammonia levels in a patient's bloodstream (and in a patient's alveoli breath) are indicative of patient renal failure and the need for dialysis. In accordance with this invention, a gas concentration of carbon dioxide is measured by light energy absorption. The threshold level for CO_2, above which alveolar breath is present, is normally 3.5 to 5.5 percent

(page 9, paragraph 0026). When a threshold level of CO_2 concentration indicative of the threshold above which alveolar breath is present, 4.5 percent for example (page 6, paragraph 0015), the concentration of ammonia is taken in order to determine its concentration in the alveolar breath and a determination made if subsequent dialysis medical treatment is required (page 1, paragraph 0003). In a preferred embodiment, light absorption wavelengths are multiplexed before spectroscopic measurement (page 16, paragraph 0042).

Issues

A single issue is presented by this Appeal.

1. Is there a suggestion to combine the references relied on in rejecting Appellant's claims in view of the fact that (1) the Culver and Phillips patents are from an art unit nonanalogous to the other cited references and (2) the references teach away from this combination?

Grouping of Claims

Claims 30 and 41 are rejected based on a combination of references that includes Culver, but not Phillips. These claims were discussed with the Examiner in an Interview dated April 13, 2005, the substance of which is set out below:

> Applicant proposed an amendment to the claims to limit the triggering step to be based on only the immediately previous measurement. Applicant noted that Culver's measurement was based on 4 preceding measurement (see columns 5 and 6). The examiner agreed and noted that such a limitation would define over the rejection based on Culver, but that an update search was necessary before deciding on ultimate allowability.

All of the other rejected claims fall in a second group where newly cited Phillips is a reference.

ARGUMENT

A. 35 U.S.C. § 103 Rejection of Claims 1, 4-6, 8, 9, 11, 13, 14 and 17-19

These claims have been rejected on obvious grounds based on the combination of a number of references. Claims 1, 4-6, 8, 10, 11, 13, 14, 17 and 19 were rejected based on a combination of three patents, Kiefer (3,830,630), in view of Forrester (5,376,555) and Phillips, and claims 1, 4-6, 8, 9, 11, 13, 14, 17 and 18 were rejected based on a combination of five patents, Gustafsson (6,038,913), in view of Kiefer, Forrester, Phillips and Culver (5,445,160).

These patents are listed below together with their USPTO classification:

Inventor	Classification
Kiefer	**23**, chemistry, physical processes
Forrester	**436**, chemistry; analytical and immunological testing
Phillips	**128**, surgery
Gustafsson	**73,** measuring and testing
Culver	**128**, surgery

B. 35 U.S.C. § 103 Rejection of Claims 20-22, 24-26, 29-34, 36, 37 and 39-42

Claims 20, 21, 22, 24-26, 29, 31-34, 36, 37, 39, 40 and 42 are rejected based on a combination of Kiefer, Forrester, Phillips and Grafton (6,192,261, class 600), while claims 20, 21, 22, 24-26, 29, 30, 32-34, 36, 37, 39, 41 and 42 are rejected based on a combination of Gustafsson, Kiefer, Forrester, Culver and Grafton.

While the different classifications of the art relied on by the Examiner may be some evidence of the improper combination of non-analogous art, the more significant argument made by appellant here is that there is no suggestion to combine these references. This is particularly

true as to the combination of the Phillips and Culver patents with the other cited patents. Appellant's amendment of April 25, 2005 was found by the Examiner "to define over the rejection based on Culver." Nevertheless, Culver is relied upon by the Examiner as showing "where a threshold is updated based on previous patient measurements." (May 19, 2005 Final Rejection at page 4.) Culver does not measure two components of breath; it simply detects whether a patient has stopped breathing (col. 3, lines 55-62). Phillips likewise does not measure two components of breath. Indeed, it does not measure any component of breath. Rather, Phillips determines changes in a patient's thoracic volume, and then filters a heart rate signal (col.. 2, lines 45-51). It is respectfully submitted that the Examiner has engaged in impermissible hindsight in looking for references that collectively disclose various aspects of the claimed invention, without citing to any teaching in the patents as to why one would combine Culver or Phillips, neither of which measure two breath components and are classified in the surgery art with the other cited patents dealing with chemical analysis and measuring. As held by the Federal Circuit in the case of *In re Geiger*, 2 U.S.P.Q.2d 1277, 1278 (1987):

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). We are convinced that the latter are not present here.

There is no suggestion to make such a combination of the Kiefer, Forrester and Culver/or Phillips references (common to all of the Examiner's § 103 rejections). Indeed, the references teach against such combination "to update the threshold."

In Kiefer, the threshold is <u>fixed</u> at 4.5%:

> filament 17 is **purposely designed** so that a 4-1/2% CO_2 content in the breath sample causes filament 17 to unbalance the bridge of which it is a part . . . . (col. 4, l. 13-15)

Thus, there is no teaching in Kiefer that the device "purposely designed" to have a fixed, static threshold of 4.5 could be modified to measure alveolar breath "based on the concentration of the first component in a previously expired breath" as disclosed and claimed by Appellant.

If the threshold were to be changed in Kiefer based on previously expelled breath, filament branch 17, specifically designed for a 4.5 threshold, would have to be removed and replaced by another filament in the electrical balance bridge capacitor between patient breaths. Stated differently, the suggested combination would render Kiefer inoperative.

Similarly, Forrester discloses a "**predetermined** threshold" (col. 5, l. 51). Forrester uses thermopile infrared detectors for measuring gas analysis, but notes that the filament sensor of Kiefer could also be used (col. 6, l. 19-23). So again, Forrester teaches a fixed predetermined threshold, and contains no suggestion that it be combined with Culver or Phillips. A copy of the claims on appeal is attached as Exhibit A.

Respectfully submitted

JONES DAY

Date: August 26, 2005

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EXHIBIT A

1. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

continuously monitoring a concentration of a first component of the breath by measuring the light energy absorbed by the first component as the breath is expired through the analysis chamber to determine when alveolar breath is in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath.

4. The method of claim 1, wherein triggering the at least one concentration measurement of the second component of the breath includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.

5. The method of claim 4, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

6. The method of claim 4, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

8. The method of claim 1, wherein the first component is carbon dioxide, oxygen, or water vapor.

9. The method of claim 1, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

10. The method of claim 1, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

11. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

continuously measuring a concentration of a first component of the breath expired through the analysis chamber by means of measuring the light energy absorbed by the first component;

comparing each measured concentration of the first component to a threshold concentration to determine when alveolar breath is in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath.

13. The method of claim 11, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

14. The method of claim 11, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

17. The method of claim 11, wherein the first component is carbon dioxide, oxygen, or water vapor.

18. The method of claim 11, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

19. The method of claim 11, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

20. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;

continuously measuring absorption of the light at the first wavelength by the first component to determine when alveolar breath is present in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath

wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.

21. The method of claim 20, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.

22. The method of claim 21, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.

24. The method of claim 20, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.

25. The method of claim 24, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

26. The method of claim 24, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

29. The method of claim 20, wherein the first component is carbon dioxide, oxygen, or water vapor.

30. The method of claim 20, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

31. The method of claim 20, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

32. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;

continuously calculating a concentration of the first component of the breath by monitoring absorption of the light at the first wavelength by the first component;

comparing each calculated spectroscopic concentration of the first component to determine when alveolar breath is present in the analysis chamber; and

triggering at least one concentration measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath

wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.

33. The method of claim 32, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.

34. The method of claim 33, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.

36. The method of claim 32, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

37. The method of claim 32, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

39. The method of claim 32, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering at least one spectroscopic measurement of the second component.

40. The method of claim 32, wherein the first component is carbon dioxide, oxygen, or water vapor.

41. The method of claim 32, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

42. The method of claim 32, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.